



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,818	06/27/2003	Robert J. Sweeney	279.636US1	8382

21186 7590 10/05/2009
SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

STOKLOSA, JOSEPH A

ART UNIT	PAPER NUMBER
----------	--------------

3762

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

10/05/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
request@slwip.com

Office Action Summary	Application No. 10/607,818	Applicant(s) SWEENEY ET AL.	
	Examiner JOSEPH STOKLOSA	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 25-27 and 58-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 25-27 and 58-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/8/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 1 is unclear if the curvatures have non-linear first and second derivatives or if the controller is performing the 1st and 2nd derivation of the sampled signal since Applicant has failed to positively recite the computation.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 6, 9, 13, 14, 17, 18, 25, 58, 59, and 60 rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney (US 4,996,984) in view of Leon et al. (US 5,365,934).
6. Sweeney discloses a defibrillation method involving determining a fibrillation cycle through the use of autocorrelation techniques (Col. 4, line 36-59). Examiner has interpreted the fundamental frequency claimed to be a mere manipulation of data that is obtained by Sweeney, since the fibrillation cycle would produce a period value and the

Art Unit: 3762

fundamental frequency is equivalent to the inverse of the period as seen in the equation $F = 1/T$ where T is the period. Although Sweeney is silent to the use of a memory coupled to the controller for determining the fundamental frequency through autocorrelation, Examiner considers this limitation to be necessarily disclosed by Sweeney's invention as it would be impossible to perform the autocorrelation without at least some portion of the signal to be stored and accessed so that it could be correlated with itself.

7. Sweeney fails to explicitly teach using the first and second derivatives of the signal for autocorrelation. Leon teaches that it is well known in the art to use the peak values above thresholds (where the peak values indicate a signal turning and is the zero crossing of the first derivative) for autocorrelation of the signal as set forth in Col. 2, line 3-24, for providing the predictable results of determining the fundamental frequency and heart rate of the cardiac signal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the first and second derivatives of the signal for autocorrelation for providing the predictable results of determining the fundamental frequency and heart rate of the cardiac signal.

8. With regard to claim 2, the size of the characteristic point would inherently be used to determine the fibrillation cycle through the use of the autocorrelation function as disclosed by Sweeney, since it is known that by autocorrelating a signal the signals sampled points are compared to find the repeating signal pattern.

9. With regard to claim 3, Sweeney discloses determining the period length of a cardiac cycle. Examiner considers this to be a rate estimator because 1 cycle is

Art Unit: 3762

equivalent to 1 heart beat. Further the term heart rate does not distinguish from the measured period length. In other words, if it is known that a cycle length is ~1 second, then a heart rate of 60 bpm is inherently known.

10. With regard to claim 14, Sweeney inherently teaches the autocorrelation of the signal in the time domain in that the signal is taken over a fixed time period (Col. 4, line 57).

11. With regard to claim 25 and 58, Examiner contends that Sweeney inherently discloses a machine accessible medium for accessing data to perform the disclosed method. The system must necessarily possess a memory for accessing the autocorrelated signals as well as selecting and determining the defibrillating stimulation parameters.

12. In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Sweeney with including an integral unit for storage and delivery of the cardiac signal analysis and defibrillation means since such a modification would provide the predictable results of an integral unit for reduction of space, power, and overall efficiency.

13. With regard to claim 60, Examiner considers Sweeney to establish a window before a characteristic point of the first series of characteristic points, since the sampling of the signal is done from some time interval $T_0 - T_1$ where the signal is sampled and the sampled points recreate the signal to be autocorrelated.

Art Unit: 3762

14. Claims 4-5, 11-12, 15, 16, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney in view of Leon as applied above.

15. With regard to claim 4-5, Sweeney fails to teach the use of telemetry coupled to the controller communicating with a programmer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Sweeney, since such a modification would provide the predictable results of performing the signal processing externally and thereby reducing the size of power requirements of an implanted device.

16. With regard to claim 12, Sweeney fails to explicitly disclose the autocorrelating parameters such as at least two factors being used from the characteristic points and finding a time overlap relationship. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Sweeney with the use of at least two factors being used from the characteristic points to autocorrelate the signal and finding a time overlap relationship, since such a modification would provide known autocorrelating techniques where multiple factors such as the amplitude of the signal or the timed relationship of the signal are used in the autocorrelating algorithm to provide the predictable results of accurate signal analysis and autocorrelation techniques.

17. With regard to claim 15, Sweeney discloses autocorrelating in the time domain, therefore it would also be obvious to one having ordinary skill in the art at the time the invention was made to autocorrelate the signal in the frequency domain, since it is known in the art that the frequency domain would provide the predictable results of

Art Unit: 3762

providing the frequency spectra content of the signal as well as noise interference reduction.

18. Although Sweeney is silent to the electrical signal being a ventricular or atrial ECG, Sweeney does teach the monitoring of ventricular arrhythmias and therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Sweeney with monitoring a ventricular rate electrogram, counting either R waves (a first characteristic series point) or P-waves (a second series characteristic point series) for providing the predictable determining tachyarrhythmia so that the proper defibrillating treatment may be determined.

19. Claims 7-8, 10, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney in view of Leon as applied above in view of Marcus (US 4,637,400).

20. Sweeney discloses the invention as claimed but fails to teach locating the center of a lobe and finding the area of the lobe to determine the frequency of the lobe. Marcus teaches that it is known to identify a lobe (Fig. 5A), calculating the area of the lobe (Col. 5, line 41-46; col. 6, line 10-17) for providing the predictable result of providing statistical data for the apparent differences in the visual curvatures observed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Sweeney with determining the area of the lobe from a center of the lobe, for providing the predictable results of providing statistical data for the apparent differences in the visual curvatures observed.

Response to Arguments

21. Applicant's arguments with respect to claims 1-18, 25-27, 58-61 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

Joseph Stoklosa
Examiner
Art Unit 3762

/Joseph Stoklosa/
Examiner, Art Unit 3762
9/29/2009